

Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 www.uspto.gov

COPY MAILED

FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK NY 10112 JUL 1: 6 2009

OFFICE OF PETITIONS

In re Patent No. 7,437,436

Issued: October 14, 2008

Application No. 09/774,694

Filed: February 1, 2001 Dkt. No.: 03500.015094. : DECISION ON APPLICATION FOR : PATENT TERM ADJUSTMENT

This is a decision on the "COMMENTS ON DETERMINATION OF PATENT TERM ADJUSTMENT", filed November 12, 2008. This matter is being properly treated under 37 CFR 1.705(d) as an application for patent term adjustment.

The request for reconsideration of patent term adjustment is **DISMISSED**.

The above-identified application matured into US Patent No. 7,437,436 on October 14, 2008. The patent issued with an adjustment of 773 days. This request for reconsideration of patent term adjustment was timely filed within two months of the issue date of the patent. See, 37 CFR 1.705(d). Patentees state that the "data presently available from the PAIR system appears to indicate an incorrect number of days determined for the USPTO Delay and/or for the Applicant's Delay. In particular, the Office's attention is directed to the calculation of the adjustment under 37 C.F.R. § 1.702(b) and 35 U.S.C. § 154(b)(1)(B) for failure to issue a patent within three years of the actual filing date of the application."

Patentees request recalculation of the patent term adjustment based on the decision in <u>Wyeth v. Dudas</u>, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008).

Under 37 CFR 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR 1.702 reduced by the period of time equal to the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. In other words, patentees are entitled to the period of Office delay reduced by the period of applicant delay.

The total period of Office delay is the sum of the period of three years delay and the period of examination delay, to the extent that these periods of delay are not overlapping.

The Office asserts that as of the time of submission of the request for continued examination (RCE) on April 23, 2007, the application was pending three years and 1,177 days. The Office asserts that certain action was not taken within a specified time frame, and, thus, the entry of a period of adjustment of 820 days is correct. It is noted that 779 days of adjustment accrued prior

to the submission of the RCE on April 23, 2007. At issue is whether patentees should accrue an additional 1,177 days of patent term adjustment for the Office taking in excess of three years to issue the patent as well as 779 days for Office failure to take a certain action within a specified time frame (or examination delay).

As an adjustment of 41 days occurred subsequent to the filing of the RCE, the Office contends that 779 days overlap. The adjustment of patent term is limited pursuant to 35 U.S.C. 154(b)(2)(A) as follows:

To the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 35 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule, 65 Fed. Reg. 56366 (Sept. 18, 2000). See, also, Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See, also, Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to

sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding § 1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3-year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See, 145 Cong. Rec. S14,718¹.

As such, the period for over three-year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the filing date of the application.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the entire period during which the application was pending before the Office, February 1, 2001, to the date that the request for continued examination was filed on April 23, 2007. Prior to the issuance of the patent, 820 days of patent term adjustment were accorded for the Office failing to respond within a specified time frame during the pendency of the application.

The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106th Cong. 1st Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999) (daily ed. Nov. 17, 1999).

At the time of submission of the request for continued examination on April 23, 2007, the application had been pending three years and 1,177 days. However, at the time of submission of the RCE on April 23, 2007, the Office had not delayed 1,177 days and then delayed an additional 779 days. Accordingly, 1,177 days of patent term adjustment (not 1,177 days and 779 days) was properly entered because the period of delay of 1,177 days attributable to the delay in the issuance of the patent overlaps with the adjustment of 779 days attributable to grounds specified in § 1.702(a). Entry of both periods is not warranted. The adjustments totalling 1,218 includes the adjustment of 41 days accorded under 37 CFR 1.702(a)(2) in connection with the non-final Office action mailed on October 3, 2007 in response to the RCE filed April 23, 2007.

In view thereof, no adjustment to the patent term will be made.

An application fee of \$200.00 is required for review of any application for patent term adjustment. See, 37 CFR 1.18(e). Accordingly, the required patent term adjustment application fee of \$200.00 has been charged to patentees' deposit account, as authorized.

Telephone inquiries specific to this matter should be directed to the undersigned at (571) 272-3205.

Alesia M. Brown

Petitions Attorney

Office of Petitions